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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,319

04/09/2004

Paul D. Wightman

59090US004

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03/13/2008

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EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

03/13/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/821,319	<b>Applicant(s)</b> WIGHTMAN ET AL.	
	<b>Examiner</b> TRISTAN J. MAHYERA	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-43 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 19-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/02/2006, 6/20/2005, 11/24/2004</u> .                        | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-43 in the reply filed on 9/20/2008 is acknowledged. Applicant's further species election of gold in the reply filed on 1/7/2008 is acknowledged.

### ***Status of Claims***

Claims 1-43 are pending. Claims 17 and 18 are withdrawn pursuant to 37 CFR 1.142(b), as being drawn to the non-elected invention. Claims 1-16 and 19-43 are examined on the merits.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/462140, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. "Particulate support material comprising at least one metal" is not found in the prior application. Priority date is set at 10/29/2003.

### ***Claim Objections***

Claims 1-43 are objected to because of the following informalities: The acronym "IRM" must be expanded in each independent claim it appears, or first usage in dependent claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 and 19-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over CARUSO et al. (US 6,479,146 see PTO-1449) in view of HEMMI et al. (Nature Immunology, 2002 see PTO-1449) and in view of HAINFELD et al. (US 5,521,289 see PTO-892)

CARURO teaches a process for preparing particles, nanoparticles and colloidal particles and shells that are bound to various inorganic and organic structures. CARURO teaches nanoparticles suitable for immunological detection methods, drug delivery systems for transport of active agents, microscopy and other areas of medicine, pharmaceuticals, magnetics and sensing methods using biologicals such as nucleic acids, proteins and immuno reactive proteins. See e.g. col 5 lines 38-46 and 63-66, col 4 lines 27-29; instant claims 1 and 2. The reference teaches that the particles if inorganic are gold, magnetic, ceramic, polymers or oxides. See e.g. col 5 lines 65-67, col 6 lines 56-62, Example 5; instant claims 1-11, 26-30 and 34-40. The permeability and density of a shell comprising colloidal particles can be controlled. See e.g. col 6

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lines 15-26; instant claims 5, 12, 13 and 34. The particles size is 640 nm with a range from 15um or less, preferably 100nm to 1um. See e.g. Example 5 and col 6 lines 31-33; instant claims 14, 15, 16, 37, 41 and 43. Pharmaceutical drugs and biologically active compounds are attached to the particle. See e.g. col 6 lines 39-40 and Example 4; instant claim 31.

CARUSO does not explicitly teach the specific species of IRMs from the instant invention or that the attachment to the particulate or solid support is a covalent bond.

HEMMI teaches an immune response modifier comprising imidazoquinoline and derivatives that functions through the activation of the TLR7. See e.g. page 196 and page 197 Results and page 199; instant claims 1, 19-25, 34, 37, 39 and 42.

HAINFELD teaches a core of solid metal atoms bonded to organic molecules. HAINFELD teaches the core is colloidal surrounded by a shell of organic groups which are suitable for covalent linking to other molecules or compounds, e.g. antibodies, antibody fragments, peptides, drugs, antigens, DNA, RNA, or other biological molecules. See e.g. col 2 lines 43-56; instant claims 3, 4, 10, 11, 26-30 and 36-42.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition comprising an IRM compound on a particulate support material comprising at least one metal, as taught by CURUSO in view of HEMMI and in view of HAINFELD. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because CURUSO and HAINFELD teach the support complex e.g. gold and HEMMI teaches the IRMs and because CURUSO and HAINFELD suggest the

attachment, particularly a covalent attachment of drugs, DNA and other pharmaceutical and medical compounds to the support. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to



be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, 10, 14-16, 19-25, 31-33, 37 and 42-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 71 of copending Application No. 10/640,904, claims 1, 18-24 and 32 of copending Application No. 10/821330, claims 1-9, 11, 12 and 14 of copending Application No. 10/821335, claims 1-3, 5-7 and 24-30 of copending Application No. 11/360071. Although the conflicting claims are not identical, they are not patentably distinct from each other because they comprise an IRM attached to a support material.

US 10/640,904 teaches the IRM is attached to a solid support. While the application does not teach the support comprises at least one metal, the teachings of HAINFELD would have motivated one skilled in the art at the time of the invention to use a support with at least one metal for the delivery of the IRM.

US 10/821330 teaches a method of enhancing the immune response to an IRM compound wherein the IRM depot preparation comprises a support material. While the application does not teach the support comprises at least one metal, the teachings of HAINFELD would have motivated one skilled in the art at the time of the invention to use a support with at least one metal for the delivery of the IRM.

US 10/821335 teaches an IRM support complex comprising an IRM compound covalently bonded to a macromolecular support material. The macromolecular support can be a metal, see '335 spec page 22 line 4.

US 11/360071 teaches an IRM moiety coupled to a targeting moiety. The IRM moiety or the targeting moiety or both may be bonded to a gold particle. See '071 spec page 31 line 24.

All these above applications either have an IRM compound on a particular support with a metal or it would have been obvious to a person of skill in the art at the time of the invention to be motivated to use a metal in the support material as suggested by HAINFELD and CURUSO.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TJM/

/Michael P Woodward/  
Supervisory Patent Examiner, Art Unit 1615